



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,608	12/14/2006	Antonio Martinez Martinez	ABG 3008	1313
30868 7590 06/26/2009 KRAMER & AMADO, P.C. 1725 DUKE STREET SUITE 240 ALEXANDRIA, VA 22314				
EXAMINER				
LEE, JAE W				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
06/26/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/550,608

Applicant(s)

MARTINEZ ET AL.

Examiner

JAE W. LEE

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/86)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application status

Claims 1-29 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-16, drawn to an in vitro method that comprises: a) the detection and/or quantification of the FGFR3 protein, of the mRNA of the FGFR3 gene, or of the corresponding cDNA in a sample of an individual, and b) the comparison of the amount of FGFR3 protein, of the mRNA of the FGFR3 gene or of the corresponding cDNA detected in a sample of an individual, with their normal reference values.

Group II, claims 17 and 19, drawn to a use of nucleotide or peptide sequences derived from the FGFR3 gene, to detect in vitro the presence of a bladder transitional cell carcinoma, to determine in vitro the stage or severity of this cancer in the individual, or to monitor in vitro the effect of the therapy administered to an individual with this cancer; or a use of a nucleotide or peptide sequence derived from the FGFR3 gene, in methods to screen for, identify, develop and evaluate the efficiency of compounds to bladder transitional cell carcinoma.

Group III, claim 18, drawn to an in vitro method to identify and evaluate the efficacy of therapeutic compounds against cancer bladder transitional cell carcinoma that comprises: a) placing in contact a culture of bladder tumour cells (with uncontrolled proliferation) with the candidate compound, in the appropriate conditions and for a suitable time for these to interact, b) detect and/or quantifying expression levels of the FGFR3 gene or the FGFR3 protein, and c) compare said expression levels with those of the control cultures of tumour cells not treated with the candidate compound.

Group IV, claims 20-22 and 24-29, drawn to an agent that inhibits the expression and/or activity of the FGFR3 protein.

Group V, claim 23, drawn to a use of any of the agents according to claims 20 or 21 in the manufacturing of a medicinal product for the treatment of bladder transitional cell carcinoma.

In addition to the above election, please elect a single agent from the list as recited in Claim 21, which represent structurally distinct molecules and these molecules do not share a special technical feature. It is noted that this is NOT a species election. Also, claims 21, 22 and 24-29 will be examined to the extent they read upon the elected agent.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Cappellen et al. (Nature Genetics, Vol. 23, pp.18-20, 1999 – cited on IDS) teach an in vitro method comprising the quantification of the mRNA of the FGFR3 gene, in a sample of an individual, and b) the comparison of the amount of the mRNA of the FGFR3 gene in a sample of an individual, with their normal reference values, i.e.,

"normal bladder and cervix epithelium" (see page 19, 2nd column, lines 2-6), which anticipates claim 1, in the recitation of "an in vitro method that comprises: a) the detection and/or quantification of the FGFR3 protein, of the mRNA of the FGFR3 gene, or of the corresponding cDNA in a sample of an individual, and b) the comparison of the amount of FGFR3 protein, of the mRNA of the FGFR3 gene or of the corresponding cDNA detected in a sample of an individual, with their normal reference values," and thus, the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are unrelated and distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Group is not required for another thereby presenting a search burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/
Examiner, Art Unit 1656

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656